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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

MINNEAPOLIS FIREFIGHTERS' RELIEF  
ASSOCIATION, NECA-IBEW PENSION TRUST  
FUND, and NECA-IBEW WELFARE TRUST  
FUND, Derivatively on Behalf of Nominal  
Defendant, JOHNSON & JOHNSON,

Plaintiffs,

vs.

WILLIAM C. WELDON, MARY SUE  
COLEMAN, PH.D., JAMES G. CULLEN,  
MICHAEL M.E. JOHNS, M.D., SUSAN L.  
LINDQUIST, PH.D., ANNE M. MULCAHY, LEO  
F. MULLIN, WILLIAM D. PEREZ, CHARLES  
PRINCE, DAVID SATCHER, M.D., PH.D.,  
ARNOLD G. LANGBO, and PETER LUTHER,

Defendants,

and

JOHNSON & JOHNSON,

Nominal Defendant.

Civil Action No.

**VERIFIED SHAREHOLDER  
DERIVATIVE COMPLAINT  
and  
DEMAND FOR JURY TRIAL**

*“It is a moral outrage for a company specifically marketing its products for children to allow a culture of neglect and irresponsibility to taint the medicines that parents and physicians trust to help children get well.”*

- Representative Darrell Issa (R – California)

***“You will quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave . . . THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!”***

**- Johnson & Johnson Instructions to Consultants Hired to Perform a “Phantom Recall”**

## **INTRODUCTION**

1. In a stunning disregard for the health and welfare of consumers across the globe, Johnson & Johnson (“J&J” or the “Company”) has, for several years, shown a systemic and wide-ranging breakdown in internal controls, and the endorsement of illicit manufacturing policies. As one of the world’s largest manufacturers and marketers of medications and other health products, J&J holds an important responsibility in the marketplace to ensure that their products and manufacturing facilities meet all applicable laws and regulations. Despite the potentially fatal consequences of misuse of the Company’s products and medications, J&J’s directors and executives fostered “a culture of neglect and irresponsibility” which recently resulted in the production of tainted household “medicines that parents and physicians trust to help children get well.”

2. This long-running course of conduct has resulted in substantial damage to J&J, including the indefinite suspension of a prominent manufacturing facility and at least six major recalls since September 2009 of some of the Company’s flagship medical products, such as Tylenol, Motrin and Benadryl, many of which are produced and marketed for children and infants.

3. Making matters even worse, J&J actively hid the extent of its problems by enlisting the services of “consultants” to quietly remove the Company’s tainted products from drugstores, thereby avoiding the financial and regulatory ramifications of a formal recall.

Through this clandestine directive, J&J not only violated a number of laws and regulations, but it also broke the basic trust of consumers by cavalierly eschewing concern for the public health through lax oversight, inadequate internal controls and compromised ethics.

4. This is hardly the first time the J&J Board learned of fundamental safety problems, but failed to cure them. In recent years, J&J has been regularly cited for violations of federal anti-kickback laws and systematic off-label marketing of J&J drugs. Thus, the Board was clearly on notice of the need for remedial action.

5. The high profile nature of its recent medication recalls put the J&J board of directors (the “Board” or “J&J Board”) on notice about the systemic problems at the Company, and yet the Board has refused to take sufficient preventive or remedial measures. Moreover, given J&J’s long history of violating the law through kick-backs and off-label marketing schemes, numerous red flags already existed for the Board to take action to prevent further widespread abuses from occurring at J&J. The Board, however, has refused to take sufficient preventive or remedial measures, and therefore, has failed to fulfill its fiduciary obligations.

### **NATURE OF THE ACTION**

6. Plaintiffs Minneapolis Firefighters’ Relief Association, NECA-IBEW Pension Trust Fund, and NECA-IBEW Welfare Trust Fund (collectively “Plaintiffs”), by and through its undersigned attorneys, submit this Verified Shareholder Derivative Complaint (the “Complaint”) against Defendants named herein.

7. This is a shareholder’s derivative action brought for the benefit of Nominal Defendant J&J, against certain members of the Company’s Board and certain of its executive officers (collectively, the “Individual Defendants”) seeking to remedy Defendants’ violations of federal and state law, including, among other violations of law, breaches of fiduciary duties

owed to the Company during a period from 2007, at the latest, through the present (the “Relevant Period”).

8. J&J engages in the research and development, manufacture, and sale of various products in the health care field worldwide. The Company is one of the largest manufacturers of medications in the world, and its products include such widely-used medications as Tylenol, Benadryl and Motrin.

9. Because the Individual Defendants breached their fiduciary duties throughout the Relevant Period, J&J suffered from a lack of institutional and internal controls. Indeed, the Board embraced the strategy undertaken by its management team as described on the Company’s website: “Executive management of Johnson & Johnson, with the support and approval of the Board of Directors, has set the fundamental strategic direction of the Company.”

10. During the Relevant Period, the Individual Defendants caused or allowed J&J to engage in an unethical and improper course of conduct concerning inadequate manufacturing processes and policies at Company facilities. One such facility is a plant that produces some of the Company’s most widely-used and important medical products, including several major children’s and infants’ medications.

11. The Individual Defendants’ illicit course of conduct led to multiple recalls of some of the Company’s most important products. Moreover, the United States Food and Drug Administration (“FDA”) has expressed repeated and continuous concerns over J&J’s internal controls and manufacturing facilities for the past several years, culminating in a report issued on April 30, 2010 that described in detail over 20 separate observations of violations and deficiencies in the Company’s manufacturing facilities at its Fort Washington, Pennsylvania plant.

12. The FDA's report stated, among other things, that despite receiving 46 consumer complaints regarding foreign materials in its medications, J&J failed to initiate "corrective and prevention" action to address these concerns. In addition, the Company failed to adopt adequate internal and institutional controls, failed to maintain adequate and safe facilities, and failed to ensure the quality, purity, identity and strength of its products. Overall, the FDA's findings conclude that J&J suffered massive failures in following current good manufacturing practices and other FDA regulations.

13. The FDA also received 775 reports of adverse events – including 30 deaths – involving J&J's recalled drugs between January 2008 and April 2010. After April 2010, the FDA received several hundred more complaints, including seven involving deaths.

14. As more information concerning J&J's problems have come to light, the public has gained an even more troubling picture of a company that has utterly failed in its obligations to provide the United States consumer with safe and reliable medications, while putting its shareholders at risk of massive fines and loss of goodwill. These concerns are reaching a crescendo as it now appears that J&J authorized a "phantom recall" in which it instructed "consultants" to quietly purchase tainted Motrin products, that were produced at its plant in Puerto Rico, in 2008 without notifying regulators, not to mention consumers, of suspected significant deficiencies in the medicine.

15. As a result of the Individual Defendants' breaches of fiduciary duties, J&J was forced to issue at least six separate recalls of products (apart from the "phantom recall"), including a recent recall on April 30, 2010 of 43 children's and infants' medications. In addition, the Company was forced to suspend indefinitely all production at its Fort Washington plant. The United States Congress has held hearings into J&J's conduct and promised to push

forward with all appropriate penalties and sanctions. The FDA stated that severe penalties, including possible criminal sanctions, are on the table. J&J is expected to incur several hundred millions of dollars in losses as a result of this conduct, not to mention a massive hit to a reputation that is over one hundred and twenty years in the making.

16. Plaintiffs bring this action on behalf of the Company to, among other things, recover damages caused by the Individual Defendants' unlawful courses of conduct and breaches of fiduciary duty. These damages include, among other things, the costs to the Company associated with recalls, lawsuits, remedial measures, damage to goodwill and increased regulatory scrutiny.

#### **JURISDICTION AND VENUE**

17. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a) as complete diversity exists between the Plaintiffs and each Defendant, and the amount in controversy exceeds \$75,000, exclusive of interest and costs. Plaintiffs are citizens of Illinois and Minnesota. Nominal Defendant J&J is a New Jersey corporation with its principal place of business located in New Jersey. The Individual Defendants, as discussed below, are believed to be citizens of states other than Illinois and Minnesota.

18. Venue is proper in this Court because J&J has its principal place of business in this District, Plaintiffs' claims arose in this District, and J&J has suffered and will continue to suffer harm in this District. Venue is also proper in this district because a substantial portion of the transactions and wrongs complained of herein, including Defendants' primary participation in the wrongful acts detailed herein, occurred in this district. One or more of Defendants either resides in or maintains executive offices in this district, Defendants have received substantial

compensation in this district by engaging in numerous activities and conducting business here, which had an effect in this district, and J&J is headquartered in this district.

## **PARTIES**

### **A. Plaintiffs**

19. Plaintiff Minneapolis Firefighters' Relief Association is, has been at all material times and continues to be, a shareholder of Nominal Defendant J&J. Plaintiff is a citizen of Minnesota.

20. Plaintiffs NECA-IBEW Pension Trust Fund and NECA-IBEW Welfare Trust Funds are, have been at all material times and continue to be, shareholders of Nominal Defendant J&J. Plaintiffs are citizens of Illinois.

### **B. Nominal Defendant**

21. Nominal Defendant J&J is incorporated under the laws of the state of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. J&J's principal activity is to manufacture and market products in the health care field.

### **C. The Individual Defendants**

22. Defendant William C. Weldon ("Weldon") has served as the Chief Executive Officer and Chairman of J&J since 2002. Weldon was elected to the Board of Directors and named Vice Chairman of the Board in 2001. Weldon joined the Company in 1971, and served in several sales, marketing and international management positions before becoming President of Ethicon Endo-Surgery in 1992 and Company Group Chairman of Ethicon Endo-Surgery in 1995. He was appointed to the Executive Committee and named Worldwide Chairman, Pharmaceuticals Group, in 1998. In fiscal year 2009, J&J paid Weldon the following

compensation as an executive: (i) salary: \$1.8 million, and (ii) all other compensation: \$30 million. Upon information and belief, Weldon is a citizen of Pennsylvania.

23. Defendant Mary Sue Coleman, Ph.D. (“Coleman”) has served as a director of J&J since 2003. Coleman is a member of the Audit Committee and the Science & Technology Advisory Committee. In fiscal year 2009, J&J paid Coleman \$230,000 in total compensation for her service as a director. Upon information and belief, Coleman is a citizen of Michigan.

24. Defendant James G. Cullen (“Cullen”) has served as a director of J&J since 1995. Cullen is the Presiding Director of the Board, Chairman of the Audit Committee and a member of the Nominating & Corporate Governance Committee. In fiscal year 2009, J&J paid Cullen \$230,000 in total compensation for his service as a director. Upon information and belief, Cullen is a citizen of New Jersey.

25. Defendant Michael M.E. Johns, M.D. (“Johns”) has served as a director of J&J since 2005. Johns is a member of the Compensation & Benefits Committee and the Science & Technology Advisory Committee. In fiscal year 2009, J&J paid Johns \$230,000 in total compensation for his service as a director. Upon information and belief, Johns is a citizen of Georgia.

26. Defendant Susan L. Lindquist, Ph.D. (“Lindquist”) has served as a director of J&J since 2004. Lindquist is a member of the Science & Technology Advisory Committee and the Public Policy Advisory Committee. In fiscal year 2009, J&J paid Lindquist \$212,000 in total compensation for her service as a director. Upon information and belief, Lindquist is a citizen of Massachusetts.

27. Defendant Anne M. Mulcahy (“Mulcahy”) has served as a director of J&J since October 2009. Mulcahy is a member of the Compensation & Benefits Committee and the



Nominating & Corporate Governance Committee. In fiscal year 2009, J&J paid Mulcahy \$80,000 in total compensation for her service as a director. Upon information and belief, Mulcahy is a citizen of Connecticut.

28. Defendant Leo F. Mullin (“Mullin”) has served as a director of J&J since 1999. Mullin is a member of the Audit Committee and Chairman of the Public Policy Advisory Committee. In fiscal year 2009, J&J paid Mullin \$240,000 in total compensation for his service as a director. Upon information and belief, Mullin is a citizen of Georgia.

29. Defendant William D. Perez (“Perez”) has served as a director of J&J since 2007. Perez is the Chairman of the Nominating & Corporate Governance Committee and a member of the Compensation & Benefits Committee. In fiscal year 2009, J&J paid Perez \$230,000 in total compensation for his service a director. Upon information and belief, Perez is a citizen of Wisconsin.

30. Defendant Charles Prince (“Prince”) has served as a director of J&J since 2006. Prince is the Chairman of the Compensation & Benefits Committee and is a member of the Nominating & Corporate Governance Committee. In fiscal year 2009, J&J paid Prince \$220,000 in total compensation for his service as a director. Upon information and belief, Prince is a citizen of Virginia.

31. Defendant David Satcher, M.D., Ph.D. (“Satcher”) has served as a director of J&J since 2002. Satcher is Chairman of the Science & Technology Advisory Committee and a member of the Public Policy Advisory Committee. In fiscal year 2009, J&J paid Satcher \$240,000 in total compensation for his service as a director. Upon information and belief, Satcher is a citizen of Georgia.

32. Defendant Arnold G. Langbo (“Langbo”) served as a director of J&J from 1991 through the end of fiscal 2009. Langbo did not stand for election to the Board in 2010. In fiscal year 2009, J&J paid Langbo \$232,000 in total compensation for his service as a director. Upon information and belief, Langbo is a citizen of Florida.

33. Defendant Peter Luther (“Luther”) has served as the President of McNeil since January 2009. From 1991 through March 2000, Luther was the franchise director of McNeil’s Consumer & Specialty Pharmaceuticals. Luther served as the President of LifeScan, another J&J subsidiary, from March 2000 to March 2006, until he became President of J&J’s North American Beauty Care division, a position he held until January 2009. Upon information and belief, Luther received substantial compensation from J&J, and he is a citizen of New Jersey.

34. Defendants Weldon, Coleman, Cullen, Johns, Lindquist, Mulcahy, Mullin, Perez, Prince, Satcher, Langbo, and Luther are collectively referred to herein as the “Individual Defendants.”

#### **DUTIES OF THE INDIVIDUAL DEFENDANTS**

35. By reason of their positions as officers and/or directors of J&J during the Relevant Period and because of their ability to control the business and corporate affairs of the Company, the Individual Defendants owed J&J and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage the Company in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of J&J and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to J&J and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the

Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

36. The Individual Defendants, because of their positions of control and authority as directors and/or officers of J&J, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Due to their positions with J&J, each of the Individual Defendants had knowledge of material non-public information regarding the Company.

37. To discharge their duties, the Individual Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of J&J were required to, among other things:

a. Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

b. Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority; and

c. When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

38. According to J&J's Principles of Corporate Governance,<sup>1</sup> the Company is governed by the values set forth in "Our Credo," and that "good corporate governance results from sound processes that ensure that our directors are well supported by accurate and timely information, sufficient time and resources and unrestricted access to management."

39. The Principles of Corporate Governance provide that the responsibilities of the Board include the duties to "select, oversee and monitor the performance of the senior management team," and to "exercise their business judgment on matters of critical and long-term significance to the Company in furtherance of what they reasonably believe to be in the best interest of the Company."

40. Similarly, J&J's Policy on Business Conduct<sup>2</sup> emphasizes the Company's purported dedication to enforcement and compliance with high ethical standards and legal regulations, providing in pertinent part as follows:

All managers shall be responsible for the enforcement of and compliance with this Policy on Business Conduct including necessary distribution to ensure employee knowledge and compliance. The board of directors or other governing body of each affiliate company shall formally adopt this Policy as its own corporate policy binding on all directors, officers and employees of the company.

\* \* \*

Consistent with our Credo and business philosophy, it is the policy of Johnson & Johnson to comply with the laws of each country in which our companies do business. It is the responsibility of each company's management and employees to be familiar with the laws and regulations that relate to their business responsibilities and to comply with them.

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<sup>1</sup> The Principles of Corporate Governance can be found at <http://www.investor.J&J.com/governance/principles.cfm>.

<sup>2</sup> The Policy on Business Conduct can be found at <http://www.investor.J&J.com/governance/conduct.cfm>.

No aspect of our business is more subject to governmental regulation than the development, manufacture, approval, sales and marketing of our health care products. Because of the complex nature of many of these regulations, management must take particular care to ensure appropriate employees are aware of regulatory requirements and take necessary steps to comply with them.

41. J&J has also adopted a Code of Business Conduct & Ethics for the members of the Board of Directors and the Executive Officers of the Company.<sup>3</sup> The Code of Business Conduct & Ethics also emphasizes the Board's responsibilities in ensuring that the Company adheres to ethical and legal regulations and J&J's policies, providing in pertinent part as follows:

Each Director and Executive Officer shall be responsible for complying with this Code. Executive Officers of the Company must comply with the Johnson & Johnson Policy on Business Conduct also.

If any Director or Executive Officer believes that a prohibited act under this Code has occurred, then he or she shall promptly report such belief to the Chairman of the Board, the Presiding Director and the General Counsel. While this is the preferred reporting procedure, any Director or Executive Officer should feel free to report any such alleged prohibited act hereunder to the Chairman of the Audit Committee or the Chairman of the Nominating & Corporate Governance Committee.

\* \* \*

Consistent with our Credo and business philosophy, it is the policy of Johnson & Johnson to comply with the laws of each country in which our companies do business. ***Each Director and Executive Officer shall comply with all applicable laws, rules and regulations, and shall use all reasonable efforts to oversee compliance by employees, other Directors and other Executive Officers with all applicable laws, rules and regulations.*** [Emphasis added.]

42. As discussed below, in addition to violating their fiduciary duties, the Individual Defendants failed to meet their responsibilities as detailed in, among other things, the Principles of Corporate Governance, the Policy on Business Conduct and the Code of Business Conduct &

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<sup>3</sup> The Code of Business Conduct & Ethics can be found at <http://www.investor.J&J.com/governance/boardconduct.cfm>.

Ethics. The Individual Defendants' illegal course of conduct constituted breaches of their fiduciary duties to J&J and resulted in significant harm to the Company.

### **SUBSTANTIVE ALLEGATIONS**

#### **A. Background of the Company**

43. J&J engages in the research and development, manufacture, and sale of various products in the health care field worldwide. The Company was founded in 1886 and is based in New Brunswick, New Jersey.

44. J&J operates in three segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics. The Consumer segment provides products used in baby care, skin care, oral care, wound care, and women's health care fields, as well as nutritional, over-the-counter pharmaceutical products, and wellness and prevention platforms under the names Johnson's, Aveeno, Clean & Clear, Johnson's Adult, Neutrogena, Roc, Lubriderm, Dabao, Vendome, Listerine, Reach, Band-Aid, Purell, Carefree, Stayfree, Splenda, Tylenol, Sudafed, Zyrtec, Motrin Ib, and Pepcid Ac.

45. J&J's Pharmaceutical segment offers products in various therapeutic areas, such as anti-infective, antipsychotic, cardiovascular, contraceptive, dermatology, gastrointestinal, immunology, neurology, oncology, urology, and virology. The Company's products in this segment include Remicade, a biologic approved for the treatment of immune mediated inflammatory diseases; Procrit, a biotechnology-derived product that stimulates red blood cell production; Levaquin, which is used in the anti-infective field; Risperdal Consta, a injectable for the treatment of schizophrenia; Concerta, a product for the treatment of attention deficit hyperactivity disorder; Aciphex/Pariet, a proton pump inhibitor; Duragesic/Fentanyl

Transdermal, a treatment for chronic pain; Velcade for the treatment of multiple myeloma; Prezista for treating HIV/AIDS patients; and Invega, a atypical antipsychotic.

46. The Company's Medical Devices and Diagnostics segment primarily offers circulatory disease management products; orthopaedic joint reconstruction, spinal care, and sports medicine products; surgical care, aesthetics, and women's health products; blood glucose monitoring and insulin delivery products; professional diagnostic products; and disposable contact lenses.

47. In 1959, J&J acquired McNeil Laboratories, a company focused on direct marketing of prescription drugs to hospitals, pharmacists, and doctors. McNeil Laboratories had introduced into the drug market Algoson, a preparation containing acetaminophen together with sodium butabarbital, a sedative, in 1953, and in 1955, it introduced Tylenol Elixir for children, containing only acetaminophen.

48. A year after J&J's acquisition of McNeil Laboratories, the Company's McNeil division was able to sell Tylenol for the first time ever without a prescription. In 1961, McNeil Laboratories moved into its Fort Washington, Pennsylvania headquarters.

49. In 1977, McNeil Laboratories created two companies: McNeil Pharmaceutical and McNeil Consumer Healthcare.<sup>4</sup> McNeil Pharmaceutical focuses on the marketing of prescription drugs, and in 1993 McNeil Pharmaceutical merged with the Ortho Pharmaceutical Corporation to form Ortho-McNeil Pharmaceutical. McNeil Consumer Healthcare markets over-the-counter and prescription pharmaceuticals including complete lines of Tylenol and Motrin IB (ibuprofen) products for adults and children.

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<sup>4</sup> All references to "McNeil" herein include McNeil Laboratories, McNeil Pharmaceutical and McNeil Consumer Healthcare.

50. McNeil currently makes a variety of over-the-counter products for the U.S. market from four manufacturing facilities in the United States and Canada. In addition to its Fort Washington plant, McNeil also currently operates plants in Lancaster, Pennsylvania; Las Piedras, Puerto Rico; and Guelph, Ontario, Canada.

**B. J&J's Long History of Violating Federal and State Laws**

**i. J&J's Kickback Schemes**

51. J&J has been plagued with ethical and legal violations in recent years. These transgressions, detailed below, have caused the Company and the Board to be on “heightened alert” for the illicit conduct complained of herein. Specifically, J&J conducted a widespread kickback scheme in order to bolster the sale of its products. Omnicare, the largest nursing home pharmacist in the United States, was used by J&J to market Risperdal® to elderly patients who suffered from dementia. Omnicare provides pharmaceuticals and related pharmacy and ancillary services to long-term health care institutions. Among the services that Omnicare engages in is the delivery of drugs to patients in nursing homes and related facilities.

52. After Omnicare delivers drugs to patients, it submits reimbursement claims on behalf of those patients to their insurers. Omnicare submits approximately 65% of these claims to Medicaid. Omnicare also employs hundreds of “consultant pharmacists.” Consultant pharmacists make recommendations to nursing home physicians about the drugs they should prescribe to nursing home residents. Consultant pharmacists became necessary after Congress decided to act to prevent the excessive use of antipsychotic drugs.

53. Under the amendment to the Social Security Act, psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least



annually an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs.

54. The Department of Health and Human Services (“DHHS”) implemented this amendment to the Social Security Act by mandating that a licensed pharmacist review the drug regimen of each resident and report any irregularities to the attending physician. During this review, the consultant pharmacists make recommendations to remove, change, or add medications.

55. J&J used Omnicare’s pharmacist consultants as a branch of their marketing department. J&J and Omnicare both used the term “intervention” to refer to the means by which Omnicare pharmacists and consultant pharmacists obtained physician authorization to switch nursing home patients from one drug to another.

56. For years, Omnicare’s primary purpose in intervention was to drive prescriptions of Risperdal®, which was used at nursing homes as a chemical restraint. The aim was to increase spending by Medicaid and other federal health care programs on J&J drugs.

57. Defendants and other J&J employees knew that it was a violation of the anti-kickback statute to offer or to pay remuneration, in any form, to induce a customer like Omnicare to purchase or to recommend J&J drugs. Similarly, Defendants and other J&J employees responsible for handling the Omnicare account understood that J&J could violate the law by using payments to customers for data as a substitute for discounts or rebates that, if disclosed, could increase J&J’s financial obligations to the Medicaid program. It was understood that it would be a kickback to bribe a customer like Omnicare for the sake of fostering a relationship or for goodwill, where the goal was always to convince Omnicare to purchase and to recommend J&J drugs.

58. At one point, J&J and Omnicare signed a multi-year performance contract which provided “incentives to Omnicare to advocate appropriate use of J&J products.” These incentives were a valuable tool for J&J to drive sales through Omnicare. For example “a \$3MM investment in rebates with Omnicare,” allowed J&J to gain “\$9MM in sales.” J&J understood that rebates were very important to Omnicare and represented approximately 60% of Omnicare’s net income. These payments, however, constituted illegal kickbacks. The value of the kickback scheme was all the Company executives considered in embracing it, disregarding not only the law but also the best interest of the public and the Company.

59. For years, J&J paid Omnicare tens of millions of dollars in market share rebates pursuant to performance agreements between the companies. Often, at Omnicare’s request, J&J paid quarterly rebates to Omnicare in advance, thus effectively providing Omnicare with interest-free loans of millions of dollars.

60. The scheme caught the attention of federal authorities after two “whistleblowers” from Omnicare filed *qui tam* actions. The U.S. Department of Justice (the “DOJ”) soon intervened in these actions, and Omnicare settled the claims against it for engaging in the kickback scheme for nearly \$100 million.

61. In its November 7, 2005 Form 10-Q, J&J first disclosed that on September 26, 2005, the Company had received a subpoena from the United States Attorney’s Office, District of Massachusetts, seeking documents related to sales and marketing of eight drugs to Omnicare, Inc., a manager of pharmaceutical benefits for long-term care facilities.

62. On September 27, 2007, the Department of Health and Human Services Office of the Inspector General filed a criminal complaint in the United States District Court for the District of New Jersey. Pursuant to the settlement between the government and the Company, in

September 2007 J&J was forced to pay \$84.7 million, and its DePuy Orthopaedics subsidiary was charged with conspiracy to violate the federal Anti-Kickback Statute and forced to enter into a deferred prosecution agreement and a Corporate Integrity Agreement in a combined resolution of criminal and civil charges for paying and offering inducements to orthopedic surgeons to use DePuy hip and knee joint reconstruction and replacement products.

63. On January 15, 2010, the DOJ filed a complaint against J&J and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (the successor in interest to Janssen Pharmaceutica Products, L.P. and Ortho-McNeil Pharmaceutical Products, L.P.) and Johnson & Johnson Health Care Systems, Inc. The complaint revealed the scope and extent of J&J's violations of applicable law.

64. The DOJ's complaint accuses the Company of violating federal false claims and anti-kickback laws among others. The DOJ is seeking treble damages and restitution of J&J's unjust enrichment. In addition, a consumer class action was filed on behalf of nursing home patients harmed by J&J's and Omnicare's conduct. The Company faces significant liability from the DOJ and the consumer actions. In addition, J&J faces liability from litigation commenced by numerous states, including Arkansas, Louisiana, Pennsylvania, South Carolina and Texas, to recoup losses suffered as a result of violations of the Medicaid Act and various state consumer protection statutes.

65. J&J subsidiary Ortho-McNeil Pharmaceutical, LLC agreed in late April 2010 to plead guilty to a misdemeanor crime and pay a \$6.14 million fine for misbranding its drugs. Another J&J subsidiary, Ortho-McNeil-Janssen Pharmaceuticals, Inc. also agreed in April 2010 to pay \$75 million to resolve claims for its illegal promotion of its drugs, specifically Topamax. J&J will also enter into a wide-ranging corporate integrity agreement with the office of Inspector

General of the DHHS. The agreement requires Ortho-McNeil-Janssen Pharmaceuticals, Inc. to increase transparency and accountability in its operations.

**ii. J&J's Off-Label Marketing Schemes**

66. In addition to its widespread kickback schemes, J&J also engaged in multiple off-label marketing schemes as well. Doctors are allowed to prescribe any drug as they see fit to treat a patient, but the FDA prohibits pharmaceutical companies from promoting off-label uses to doctors. As such, a drug manufacturer cannot legally label or promote a drug without prior FDA approval.

67. Over the last decade, J&J has engaged in multiple off-label marketing schemes, which has drawn the scrutiny of federal investigations. Specifically, J&J's off-label marketing schemes, included the following products: Topamax, Risperdal, Natrecor, and biliary stents.

68. From approximately 1996 through 2007, J&J, through its subsidiary Cordis Corporation ("Cordis"), pursued illegal off-label marketing related to medical devices known as biliary stents. In September 2006, a *qui tam* action was filed on behalf of, *inter alia*, the United States in the Northern District of Texas, under the False Claim Act seeking damages, penalties and other remedies related to the off-label marketing concerning the biliary stents pursued by several companies, including J&J and its subsidiary, Cordis.

69. In its 2003 Annual Report, J&J reported that it was under investigation for its off-label marketing of Topamax and Risperdal. Weldon, Coleman, Cullen, Lindquist, Mullin and Satcher signed the 2003 Form 10-K, which demonstrates that they had notice of J&N's off-label marketing scheme. The J&J Board, however, did nothing in response to this investigation and took no actions to prevent illegal off-label marketing schemes from occurring.

70. J&J's subsidiary, Ortho-McNeil Pharmaceutical, Inc. then continued to market Topamax for off-label uses by staging "Consultant Conferences". Indeed, reports exist that over 75% of all prescriptions for Topamax were off-label. J&J's off-label marketing scheme related to Topamax caused J&J to plead guilty to a misdemeanor and pay a \$6.14 million criminal fine. J&J further agreed to pay \$75.37 million to resolve civil claims under the False Claims Act.

71. Likewise the disclosure in its 2003 Annual Report did not stop J&J from continuing to promote Risperdal for off-label uses. As a result, J&J received more subpoenas and/or requests for information related to the marketing and sales of Risperdal after the initial January 2004 subpoena. In this regard, both J&J's 2005 and 2006 Annual Reports detail further subpoenas and investigations related to the off-label marketing of Risperdal.

72. In its August 2005 Form 10-Q, J&J disclosed that the government was investigating its marketing practices related to Natecor, which was a drug developed by Scios Inc. J&J bought Scios Inc. in 2003 for \$2.5 billion, and knew about the Scios Inc.'s aggressive off-label marketing schemes at the time that the Board approved this acquisition.

73. In its 2007 Annual Report, J&J reported that the Company had received separate subpoenas from the U.S. Attorney's Offices located in Philadelphia, Boston and San Francisco relating to the marketing and sales of Topamax, Risperdal and Nactreor through three of J&J's subsidiaries.

74. In its 2008 Annual Report, J&J disclosed that in June 2008, the Company received a subpoena relating to the marketing of biliary stents by Cordis from United States Attorneys' Office for the District of Massachusetts.

75. The Company faces liability exposure in the amount of billions of dollars as a result of its unlawful off-label promotion of these drugs.

**C. Background of the FDA Oversight of Drug Manufacturing**

76. The FDA is an agency of the United States Department of Health and Human Services and is responsible for regulating drug manufacturing in the United States. Under the Federal Food, Drug, and Cosmetic Act, the FDA is charged with, among other things, ensuring that drugs marketed in the United States are safe and effective, and are manufactured in accordance with current Good Manufacturing Practice (cGMP).

77. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations are intended to ensure purity, potency, and quality of drug products, and to prevent unsafe products from reaching consumers. The FDA enforces cGMP regulations and defines them as follows:

cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing, processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufactures of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mixups, deviations, failures and errors. This assures that drug products meet their quality standards.

78. Under the cGMP regulations, each manufacturer sets specifications for its own products for such factors as potency, stability and purity, and puts in place a quality system that ensures those specifications are met. Critical to the cGMP process is that a company must meet its own standards. A violation of cGMP indicates that a breakdown in a manufacturer's quality system has occurred and is an indication that a company needs to take effective steps to fix the problem promptly.

79. The FDA inspects facilities to ensure compliance with cGMP standards. These inspections occur on average for domestic facilities every two to three years. The FDA increases the frequency of inspections for facilities when warranted by past problems or by products that are difficult to manufacture or are especially high risk. When on site, FDA inspectors identify gaps in manufacturing standards and discuss with companies how they can fix them.

80. Firms may choose to recall products when there are cGMP violations, especially when those violations have a significant impact on product quality or safety. For drugs, patterns of non-compliance that put the public's health at risk leads to appropriate enforcement action by the FDA, including warning letters, seizures, injunctions and, in the most extreme cases, criminal prosecution.

**D. The Individual Defendants' Wrongful Course of Conduct**

81. During the Relevant Period, McNeil's manufacturing processes have come under scrutiny from the FDA for failing to adhere to cGMP regulations, leading to grave concerns over the quality of the products produced at McNeil's manufacturing facilities. The target of the FDA's quality concerns include some of the Company's most well-known and widely-used products, such as Tylenol, Motrin, Zyrtec and Benadryl, and also include versions of these products that are marketed for children and infants.

82. Recent product recalls are not the first sign of widespread problems with McNeil's manufacturing facilities. In 2008, an FDA report outlines a heightened number of complaints about consumer tablets of Tylenol Arthritis. The report also explains McNeil's failure to timely report contamination at its facilities or follow through on commitments related to product recalls. Among other things, the report notes that written procedures were not followed and internal investigations were deficient.

83. As a result of the Company's massive manufacturing deficiencies and the complete lack of institutional and internal controls at its McNeil subsidiary, J&J has suffered six major product recalls since September 2009, as follows.

84. In September 2009, J&J recalled 21 different infant and children's products after an FDA inspection of McNeil's Fort Washington plant found that the unused portion of an ingredient contained *B. capacia* bacteria. The Company stated in its letter dated September 18, 2009 to healthcare professionals:

I am writing to inform you that, in consultation with the U.S. Food and Drug administration (FDA), McNeil Consumer Health care is voluntarily initiating a recall of certain lots of Children's and Infants' TYLENOL® products that were manufactured between April 2008 and June 2008.. . The company has implemented this recall because examination of bulk raw material detected that one of the inactive ingredients did not meet internal testing requirements. Specifically, the gram-negative bacteria *Bukholderia capacia* (*B. capacia*) was detected.

85. In November 2009, five lots of Tylenol Arthritis Pain 100 count with the EZ-open cap, which were produced at McNeil's plant in Puerto Rico, were recalled for unusual odor leading to nausea, stomach pain, vomiting and diarrhea.

86. In December 2009, the prior recall was expanded to include all product lots of Tylenol Arthritis Pain caplet 100 count bottles with the red EZ-open cap, which were also manufactured at McNeil's plant in Puerto Rico.

87. In January 2010, the recall was widened to an undisclosed number of Tylenol, Motrin and other over-the-counter drugs, which McNeil produced at its plant in Puerto Rico, after complaints of consumers feeling sick from an odor. In response to these recalls, the FDA stated that the Company did not act in a timely manner because customers began complaining about this odor in early 2008, but the Company only made a limited investigation at that time. Karen Hirshfield, the acting branch chief of the FDA's Recalls and Shortages Branch, stated that



McNeil failed to report this issue to the FDA until nearly a year later. The FDA then sent McNeil a warning letter in January 2010, which stated:

Your initial investigation into the root cause of the odor was unjustifiably delayed and terminated prematurely. Numerous complaints were received over a four month period in 2008 before they were considered a trend and before actions were initiated to determine the root cause. When microbiological testing in August 2008 did not support an initial speculation that microbial contamination was the root cause of the odor, the investigation was closed. No other possible root causes were pursued. Your firm lacked adequate justification for this decision.

88. In May 2010, approximately 50 children's and infants' versions of these nonprescription medicines were also recalled because of quality and safety concerns. Following the pediatric medicine recall, J&J suspended production at McNeil's facility in Fort Washington, Pennsylvania, which manufactured the pediatric drugs.

89. In June 2010, the Company added five additional lots of Benadryl and Tylenol medications to the recall, stating that the drugs were "inadvertently omitted from the initial recall action" of January 15, 2010.

90. In addition to the six major recalls by J&J, it also instituted three additional recalls at the warehouse and retail level in March 2010, which involved Children's Zyrtec, Children's Tylenol, Infants' Tylenol, Infants' Motrin and Zyrtec Itchy Eye Drops for problems including: (i) the thickness of the product's bottle failing to meet standard specifics, (ii) labeling defects that would lead to the printed expiration date on the bottle becoming illegible, and (iii) testing samples that did not meet product specifications.

91. These actions have led to a formal congressional inquiry of the Company's practices, an FDA investigation and significant FDA enforcement actions, including possible criminal prosecutions. Even more troubling, as this saga has drawn on, additional information has come forward indicating that J&J authorized a "phantom recall" of its deficient products in

which it instructed consultants to quietly purchase these products without alerting regulators or consumers.

92. As a J&J representative testified before Congress, the Board is well-informed and entirely engaged in the J&J product recalls. Indeed, Weldon himself posted an open letter to consumers about the McNeil recall on the Company's blog. Most product recalls were widely broadcast through numerous medians – publications the Board was well aware of. The problems underlying product recalls are of the severity that even if the Board was unaware of their existence then it was only through willful blindness or a reckless disregard. The Board being fully aware of the product recalls themselves, had a clear duty to address the underlying causes effectively and expediently. The Board failed to do either.

93. Because of the Individual Defendants' acquiescence to or promotion of illegal and unethical conduct, J&J stands to lose hundreds of millions of dollars in losses, significant regulatory and legal penalties, as well as a taint to its reputation as a leading manufacturer of medications worldwide that will effect Company sales for years to come.

### **iii. The FDA Form 483 Inspection Report**

94. J&J was aware of McNeil's quality control and organizations problems for some time, and these issues led to the issuance of several recalls of the Company's Consumer segment products, including six major recalls between September 2009 and June 2010. In fact, Deborah Autor, the FDA's director with the Office of Compliance, stated that the FDA met with J&J's senior management, including Luther and the Company Group Chairman for OTC, in February 2010 in response to the FDA's warning letter to the Company concerning the recall of its products from McNeil's plant in Puerto Rico. During this meeting, Ms. Autor said that "we [the FDA] expressed serious concerns about McNeil's manufacturing operations." Indeed, this

meeting drove the FDA to inspect McNeil's other plants, including its Fort Washington plant, more quickly.

95. More specific details of J&J's problems concerning McNeil's quality controls emerged on April 30, 2010, when the FDA issued a Form 483 inspection report (the "Form 483") concerning its investigation of McNeil's manufacturing facilities and processes.

96. The Form 483 was based on inspections of McNeil's Fort Washington plant between April 19, 2010 and April 30, 2010. The Fort Washington plant manufactures various medications, including children's and infants' versions of Tylenol, Motrin, Zyrtec, and Benadryl. These products represent a vital portion of J&J's Consumer segment.

97. The Form 483 reported severe safety and process concerns at the McNeil plant that affected the products produced at the plant. In fact, the Form 483 described 20 observations of deficiencies in the plant's processes and products, stating in pertinent part as follows (with redactions from the original document):

- Observation 1: "The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically . . . The Quality Control Unit (QA) authorities most responsible for overseeing daily operations at the Fort Washington facility did not ensure that the responsibilities of the Analytical, Microbiological, Compliance, and Quality Assurance departments were enforced for rejection and withholding from approval any raw material component that contained "known" contamination of gram negative organisms. Raw material (b) (4) (4), lot (b) (4) had known contamination with gram negative organisms and were approved for use to manufacture several finished lots of Children's and Infant's Tylenol drug products, which remain within the expiration date(s) on the market. Responsible firm officials did not adhere to GMP regulations per (b) (4) (4) for (b) (4) (b) (4) in that no Quality Notification was implemented regarding the rejection of contaminated lots of (b) (4) (4).

"QA and Compliance Department overall responsibilities per the firm's (b) (4) is deficient as follows: It does not maintain adequate laboratory facilities for the testing and approval (or rejection) of components and drug products; it neglects review and approval of validation protocols regarding changes in product

processes and equipment to determine when revalidation is or should be warranted; it is default in investigations, tracking, trending and maintenance of consumer complaint follow-up; and it lacks trending of products, components (i.e., water), and complaints to demonstrate a broad perspective to assure plant conformance with CGMPs.”

- Observation 2: “There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

“Specifically . . . Lack of process validation for the manufacture of Infant’s Dye-Free Tylenol Suspension Drops, Cherry, Formula (b) (4) 80 mg/0.8 mL. The compounding and transfer of the (b) (4) batch size suspension to the (b) (4) hold tank is not in a “state of control”. The firm did not effectively evaluate the change in the manufacturing process (agitation and tank level time to shut off a agitator) when the batch size was increased from (b) (4) into a (b) (4) hold tank and/or when the hold tank size used for a (b) (4) batch was decreased from a (b) (4) to a (b) (4) hold tank.”

- Observation 3: “Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.”
- Observation 4: “Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.”
- Observation 5: “Written production and process control procedures are not followed in the execution of production and process control functions.

“Specifically . . . (b) (4) requires a CAPA (Corrective Action Preventive Action) to be initiated when systemic GMP issues or significant trends have been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends . . . No CAPA was initiated for the following batches from May 2009 to April 2010 where foreign material, particulate matter and/or contamination were observed...

“No CAPA was initiated for -46 consumer complaints regarding foreign materials, black or dark specks from June 2009 to April 2010.”

“(b) (4) section (b) (4) requires a (b) (4) metrics review of all new CAPAs, closed CAPAs, CAPAs open for more than (b) (4), and CAPAs exceeding the due date for review. No (b) (4) Metrics for CAPAs was completed.

“No CAPA was completed for QN (b) (4) for OOS on (b) (4)”

- Observation 6: “There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.”
- Observation 7: “GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.”
- Observation 8: “Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.”
- Observation 9: “Each container of component dispensed to manufacturing is not examined by a second person to assure that the weight or measure is correct as stated in the batch records.”
- Observation 10: “Strict control is not exercised over labeling issued for use in drug product labeling operations.”
- Observation 11: “There is no written testing program designed to assess the stability characteristics of drug products.”
- Observation 12: “Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.”
- Observation 13: “Adequate lab facilities for testing and approval or rejection of components and drug products are not available to the quality control unit.”
- Observation 14: “Laboratory records do not include complete records of the periodic calibration of laboratory instruments, gauges, and recording devices.”
- Observation 15: “Written specification for laboratory controls do not include a description of the sampling procedures used.”
- Observation 16: “Samples taken of in-process materials for determination of conformance to specifications are not representative.”
- Observation 17: “Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected.”
- Observation 18: “Components are not microscopically examined when appropriate.”
- Observation 19: “Records are not kept for the maintenance and inspection of equipment.”

- Observation 20: “The persons double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log.”

**iv. J&J’s Massive Recall of Children’s and Infants’ Medications**

98. In the wake of the dissemination of the Form 483, on April 30, 2010, McNeil implemented a voluntary recall of infant and children’s liquid products due to manufacturing deficiencies that may affect the quality, purity or potency of the medications. The recall involved all unexpired lots of seven products in 43 different flavors and sizes, including Tylenol Infants’ Drops, Children’s Tylenol Suspensions, Infants’ Motrin Drops, Children’s Zyrtec liquids in bottles and Children’s Benadryl Allergy liquids. Operations at the Company’s Fort Washington plant were suspended indefinitely. Five additional lots of Benadryl and Tylenol medications were added to the recall on June 16, 2010.

99. In a press release issued the day after the recall notification on May 1, 2010 entitled “FDA Provides Consumer Advice Following Recall of Products for Infants and Children,” the FDA provided additional guidance and information regarding the McNeil recall. The press release stated that the reasons for the recall were that “[s]ome of the products included in the recall may contain a higher concentration of active ingredient than specified; others contain inactive ingredients that may not meet internal testing requirements; and others may contain tiny particles.”

100. Also in the press release, Margaret A. Hamburg, M.D., the Commissioner of Food and Drugs, stated the following:

We want to be certain that consumers discontinue using these products and that they know what to do if they have concerns about a specific product. . . While the potential for serious health problems is remote, Americans deserve medications that are safe, effective and of the highest quality. We are investigating the products and facilities associated with this recall and will provide updates as we learn more.

101. On May 2, 2010, a *Washington Post* article entitled “J&J Division Recalls 43 Medicines for Kids” shed additional light on the problems the Company was experiencing at the McNeil plant:

A division of Johnson & Johnson is recalling 43 over-the-counter medicines made for infants and children -- including liquid versions of Tylenol, Motrin, Zyrtec and Benadryl -- after federal regulators identified what they called deficiencies at the company's manufacturing facility.

*The voluntary recall, which was announced late Friday by McNeil Consumer Healthcare, affects hundreds of thousands of bottles of medicine in homes and on store shelves throughout the United States and its territories and in nine other countries -- a vast portion of the children's medicine market.*

The Food and Drug Administration is advising parents and caregivers to stop using the affected products, although Commissioner Margaret A. Hamburg called the potential for serious health problems resulting from the medications “remote.”

FDA inspectors had begun a routine inspection April 19 in the company's Fort Washington, Pa., plant when they noticed “manufacturing deficiencies” that triggered the recall, said Douglas Stearn, a senior FDA official.

Stearn said the plant's manufacturing process was “not in control,” a term regulators use to describe flawed procedures that affect the composition of medicine. Federal investigators do not know when the problems at McNeil began, but Stearn said that “this does go back in time” and that “we have to try to figure that out.”

While the FDA investigates, McNeil has suspended operations at the facility. In a statement, the company said: “Some of the products included in the recall may contain a higher concentration of active ingredient than is specified; others contain inactive ingredients that may not meet internal testing requirements; and others may contain tiny particles.” It said the problems may affect “purity, potency or quality.”

Marc Boston, a McNeil spokesman, would not discuss the deficiencies cited by the FDA or say when the manufacturing facility was shut down. The company also declined to disclose the amount of products affected by the recall. In addition to the United States, Puerto Rico and Guam, the medicines were sold in Canada; the Dominican Republic; Dubai, in the United Arab Emirates; Fiji; Guatemala; Jamaica; Panama; Trinidad and Tobago; and Kuwait.

A complete list of recalled products is on the company's Web site.

McNeil received consumer complaints associated with some of the recalled medicines, but the company's decision to pull them was not made on "the basis of adverse medical events," said Boston, who declined to elaborate.

\* \* \*

This is at least the third major recall of Tylenol products by McNeil since 2008.

In January, McNeil recalled 49 types of Tylenol products made for adults and two Tylenol products made for children after consumers complained of a mold-like odor and of temporary and minor nausea, stomach pain, vomiting and diarrhea. The company determined that some of the medicines had been contaminated by trace amounts of a chemical that is sometimes present on shipping and storage material.

In 2008, McNeil recalled 21 types of children's and infants' Tylenol liquid products, saying that although the products met internal standards, an unused portion of one inactive ingredient did not meet all quality standards. [Emphasis added.]

102. On May 4, 2010, the *Associated Press* published an article entitled, "FDA: J&J Failed to Test Tylenol for Contamination." The article stated in pertinent part as follows:

Federal health regulators say Johnson & Johnson managers failed to test for contamination of more than 40 varieties of children's cold medicines recalled over the weekend.

An inspection report released Tuesday by the Food and Drug Administration lists more than 20 manufacturing problems found at the Fort Washington, Pa., plant where the formulas were produced. The recalled products include children and infant formulations of Tylenol, Motrin, Zyrtec and Benadryl.

FDA inspectors visited the plant in mid-April and wrapped up their inspection Friday. J&J issued its "voluntary" recall later that night.

Among other problems, FDA inspectors said the company did not have laboratory facilities to test drug ingredients and failed to follow up on customer complaints.

103. On May 5, 2010, *Bloomberg* published an article entitled, "J&J Failed to Safeguard Children's Medicines at Plant." The article described the deficiencies in McNeil's manufacturing processes and reported on the news that a hearing on the issue was scheduled before the House Oversight and Government Reform Committee:



Johnson & Johnson may have used bacteria-tainted materials in making more than 40 types of children's pain and allergy medicines recalled last week, U.S. regulators said, prompting a congressional inquiry.

***The company's McNeil Consumer Healthcare unit failed to protect those drugs from possible contamination or correct manufacturing deficiencies at its Fort Washington, Pennsylvania, production plant,*** Food and Drug Administration officials said yesterday in a conference call with reporters. None of the products tested positive for bacteria, though FDA inspectors found microorganisms in some raw materials used as inactive ingredients in the drugs, said Deborah Autor, director of compliance at the FDA's Center for Drug Evaluation and Research.

***"This is yet another example of the need for companies to take full accountability for the quality of their drugs and of the serious consequences that can happen when companies do not do so,"*** Autor said.

Lawmakers said today they will schedule a hearing on the recall before the House Oversight and Government Reform Committee.

#### Plant Conditions

The panel intends to question "the conditions of the manufacturing plant and controls put in place by the drug company's management, and about whether FDA's inspection and recall procedures were sufficient," Representatives Edolphus Towns and Darrell Issa said today in a joint statement. Towns, a Democrat from New York, is chairman of the panel and Issa, of California, is its senior Republican.

J&J recalled some types of infant and children's Tylenol, Motrin, Zyrtec and Benadryl because of "manufacturing deficiencies" that could affect quality, purity or potency of the drugs, the FDA said May 1. The recall involved over-the-counter drops and liquids in sizes ranging from 0.5 ounces (14 milliliters) to 4 ounces, J&J's McNeil unit said in a separate statement on April 30.

\* \* \*

"You've got a company that's considered one of the premier companies, that's spent something like 100 years building its reputation," Les Funtleyder, an analyst with Miller Tabak & Co., said yesterday in an interview. ***"This is the kind of thing that can hurt that."***

#### Production Suspended

J&J, the world's largest health products company, said it suspended production at the Pennsylvania plant on April 30 when it announced the recall. The company

said again in a statement yesterday that it won't resume operations until corrective actions have been taken in consultation with the FDA.

\* \* \*

***J&J failed to take action after receiving 46 consumer complaints in the past 10 months about "foreign materials, black or dark specks" in the products,*** the FDA said in a 17-page inspection report posted yesterday on its website. [Emphasis added.]

104. On May 27, 2010, *ABC World News* published an article entitled "Children's Tylenol Recall: Did 'Culture of Mediocrity' at McNeil Labs Affect Children's Medicines?" stating that J&J's recall involved 136 million bottles of medicine from the shelves, which included 70% of its products that it marketed for children and infants, including Children's Tylenol, Infant's Tylenol, Children's Motrin, Children's Zyrtec and Children's Benadryl.

**v. The Congressional Response to J&J's Troubles**

105. On May 7, 2010, *Reuters* published an article entitled, "House Panel Is Investigating J.&J. Recalls." The article provided as follows:

Lawmakers requested information on Thursday from regulators about Johnson & Johnson's recall of Children's Tylenol and other over-the-counter pediatric medicines, saying ***the company's repeated recalls "point to a major problem" with production.***

The House Committee on Oversight and Government Reform has opened an investigation after Johnson & Johnson recalled 40 widely used children's pain and allergy medications, saying some might have a higher concentration of their active ingredients, while others might be contaminated.

In an F.D.A. report issued Tuesday, inspectors said they had found thick dust, grime and contaminated ingredients at the plant that produces Children's Tylenol and dozens of other products recalled last week.

Johnson & Johnson has had four recalls of over-the-counter medicines in the last year.

***"Taken together, these recalls point to a major problem in the production of McNeil products,"*** the committee chairman, Edolphus Towns, Democrat of New York, and the panel's ranking Republican, Darrell E. Issa of California, said in a

statement, referring to the company's consumer health care unit. [Emphasis added.]

106. On May 11, 2010, *Bloomberg* published an article entitled, "J&J Recall May Cost \$300 Million Analysts Estimated." The article provided analysis as to the costs that the Company would incur as a result of the recall:

Johnson & Johnson's recall of children's medicines may cost \$200 million to \$300 million, according to Chief Financial Officer Dominic Caruso.

The estimated cost suggested by analysts "is not unreasonable," Caruso said today at the Bank of America Merrill Lynch Health Care Conference in New York. The New Brunswick, New Jersey-based company voluntarily recalled more than 40 types of pediatric pain and allergy drugs on April 30 because of contamination at a plant in Fort Washington, Pennsylvania.

FDA inspectors found dirty conditions and microorganisms in raw materials used to make over-the-counter liquid medicines during an inspection of the facility last month. J&J's McNeil Consumer Healthcare division is still investigating and doesn't know when the plant will reopen, Caruso said.

107. Despite Caruso's assurances that the contamination was "plant specific," the FDA widened its investigation of McNeil to determine the pervasiveness of the manufacturing problems. On May 18, 2010, *UPI* published an article entitled, "FDA Widens Probe of McNeil Drugs." The article stated as follows:

The federal government says it's expanding an investigation that led to the shutdown of a Johnson & Johnson drug plant in Fort Washington, Pa.

Johnson & Johnson closed the plant this month and recalled about 50 children's versions of non-prescription drugs, including Tylenol, Motrin and Benadryl, made at the plant by the company's McNeil Consumer Healthcare unit.

The children's products could contain tiny metal particles, an incorrect amount of ingredients and ingredients that don't meet testing requirements, McNeil said in its recall.

The recall of the children's medicines was the third by McNeil since September.

***The U.S. Food and Drug Administration said Monday it now is conducting a companywide investigation to determine whether similar problems exist at other McNeil plants.***

McNeil, in an e-mail Monday to CNNMoney.com, said the company was cooperating with the FDA and conducting its own quality assessment. [Emphasis added.]

108. On May 19, 2010, *Bloomberg* published an article entitled, “Congress to Hold J&J Hearing Even If Weldon Is Absent.” The article provided details as to the severity of McNeil’s manufacturing problems and stated in pertinent part as follows:

The May 27 congressional hearing set to probe the recall of several Johnson & Johnson children’s medicines won’t be delayed even if Chief Executive Officer Bill Weldon can’t attend, U.S. Representative Edolphus Towns said.

Towns, a New York Democrat and chairman of the House Committee on Oversight & Government Reform, declined to postpone the hearing as requested by U.S. Representative Darrell Issa of California. Issa, the top Republican on the House committee, asked for the delay in a letter to Towns today so that the J&J executive could attend.

***“This matter is far too serious, and what we have already uncovered is so troubling that we cannot delay this hearing,”*** Towns said in an e-mailed statement today. “If necessary, the committee will have Mr. Weldon testify as a witness at a future hearing.”

\* \* \*

#### Plant Deficiencies

Johnson & Johnson on April 30 recalled some types of infant and children’s Tylenol, Motrin, Zyrtec and Benadryl. The Food and Drug Administration said May 1 that the recall was the result of manufacturing deficiencies and warned consumers to stop taking the medicines. FDA inspectors found tainted raw materials last month at a plant run by J&J’s McNeil Consumer Healthcare unit, and the drugmaker failed to protect medicines from possible contamination, agency officials have said.

***“There is some indication that this problem may be far more serious than previously known,”*** Issa wrote today. ***“According to credible sources, the McNeil manufacturing facilities presently under investigation may be ‘out of control’ and not following internal standard operating procedures, much less FDA regulations.”*** [Emphasis added.]

109. On May 27, 2010, additional reports began to surface that provided additional details as to the extent and duration of McNeil's issues. For instance, on this date, the *Associated Press* published an article entitled, "FDA Data Shows J&J Knew of Motrin Problems in 2008." The article stated in pertinent part as follows:

Food and Drug Administration documents obtained by the Associated Press show ***Johnson & Johnson learned of problems with the potency of its Motrin formula in 2008, but did not recall the product until July the following year.***

House lawmakers are investigating J&J after last month's recall of more than 40 varieties of children's medicine, some which contained tiny particles of metal.

That recall was the latest in a series that threaten to tarnish J&J brands like Tylenol and Benadryl.

Lawmakers plan to question a J&J executive Thursday about the latest problems as well as a 2009 recall.

***The FDA documents show J&J learned of problems with some Motrin formulas in November 2008, but did not recall them until being prodded by the FDA in July 2009.*** [Emphasis added.]

**vi. The J&J "Phantom Recall"**

110. Even more troubling, evidence is mounting that, despite being aware of significant problems with the quality and safety of its products, the Company failed to issue a recall to take these products off the market and away from consumers. Rather, McNeil ordered consultants to quietly purchase these products from drug stores so that the Company would not have to notify regulators of the manufacturing deficiencies. In effect, this action constituted a "phantom recall" that did nothing to alert the public of the products' quality problems.

111. A June 14, 2010 article published by *Bloomberg* and entitled, "Head of Johnson & Johnson unit recommended the buyback of recalled drug" detailed a May 27, 2009 email from Luther to six McNeil employees to go ahead with a "market with draw of Motrin," writing "Let's make this happen ASAP."

112. A May 27, 2010 article published by *Bloomberg* and entitled, “J&J ‘Phantom Recall’ Shows Motrin Troubles Go Back,” discusses the implications of the Company’s course of conduct, including that the FDA is considering initiating criminal proceedings against the Company. The article provides in pertinent part as follows:

Johnson & Johnson’s manufacturing lapses, which caused 40 types of children’s drugs to be pulled from store shelves this month, date to 2008 when there was a “phantom recall” of the painkiller Motrin, a lawmaker said.

*Consultants to J&J’s McNeil Consumer Healthcare unit tried in August 2008 to retrieve large quantities of 88,000 packages of Motrin from stores without notifying regulators*, Representative Edolphus Towns said today at a hearing. *The drugmaker told the consultants to “simply act like a regular customer,”* according to a document released by the House Oversight and Government Reform Committee. Regulators became aware that the drugs weren’t dissolving properly three months later, said Towns, a New York Democrat and committee chairman.

The hearing was called by the oversight committee to investigate the May recall of infant and children’s Tylenol, Motrin, Zyrtec and Benadryl. U.S. Food and Drug Administration investigators found tainted raw materials during an April plant inspection, officials said. An agency official said during the hearing that J&J faces enforcement actions that may include criminal penalties.

‘Moral Outrage’

*“It is a moral outrage for a company specifically marketing its products for children to allow a culture of neglect and irresponsibility to taint the medicines that parents and physicians trust to help children get well,”* Representative Darrell Issa of California, the committee’s ranking Republican, said in his opening statement.

In the 2008 incident, McNeil hired contractors to perform a “statistical sampling,” according to FDA documents released at today’s hearing. The agency later learned the “contractor was purchasing” the Motrin in stores, the documents said.

Nine months later, McNeil initiated a recall of the Motrin products after the FDA learned about the contractors’ activities. *“We had been informed that they were going to look if any was out there on the shelves,” said Joshua Sharfstein, the FDA’s principal deputy commissioner, in an interview during a break in the hearing. “We didn’t realize they were going around buying it up and telling people to act natural. It just was strange, so we thought, ‘if you’re going to do that, you might as well do a recall.’”* [Emphasis added.]

113. The committee also released a document staff members described as instructions from J&J to the consultants, which states as follows:

You will quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave. You should simply “act” like a regular customer while making these purchases. **THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!** If asked, simply state that your employer is checking the distribution chain of this product and needs to have some of it purchased for the project.

This document is clearly of the nature that it cannot be distributed without high-level management approval.

114. In addition, during the congressional hearing, Sharfstein stated that the agency has “had growing concerns” about McNeil’s production quality, and began inspecting its facilities with increasing frequency. He further stated that the company has shown “a pattern of non-compliance,” and the agency “forced major changes to protect the public.” Sharfstein also said that in addition to possible criminal penalties, the FDA also is considering possible injunctions or seizures.

115. On June 3, 2010, Edolpus Towns sent letters to Defendant Weldon, J&J’s CEO and Chairman, L. David Mounts, the CEO of Inmar, Inc, and Sean P. Davoren, President and CEO of WIS concerning their involvement with J&J’s phantom recall and demanding the production of documents related to such recall.

**vii. The FDA’s Extensive Investigation of J&J**

116. As mentioned in the article above, on May 27, 2010, Joshua M. Sharfstein, M.D., the Principal Deputy Commissioner of the FDA, provided a statement before the U.S. House of Representatives’ Committee on Oversight and Government Reform regarding the FDA’s regulation of drug manufacturing in general and, specifically, the FDA’s oversight of McNeil and lessons learned from the ongoing investigation into quality concerns at McNeil.



117. In his testimony, Mr. Sharfstein stated that for “several years, the FDA has had growing concerns about the quality of [McNeil’s] manufacturing process. These concerns have led to a number of unsatisfactory inspections and consumer recalls. FDA has inspected the company’s facilities with an increased frequency, and in February 2010, the [FDA] took the extraordinary step of convening a meeting with the management of the parent company, Johnson & Johnson, to express concern about a pattern of non-compliance.”

118. Mr. Sharfstein provided an overview of the FDA’s extensive investigation into McNeil’s manufacturing processes, beginning prior to 2009 through the recent events in April and May of 2010. Mr. Sharfstein’s statement provides in pertinent part as follows:

**Prior to 2009.** *Before 2009, FDA investigators identified several problems with cGMP compliance at facilities run by McNeil. These problems included laboratory controls, equipment cleaning processes, and a failure to investigate identified problems.* The company generally fixed the specific problems, and the Agency inspected the firm regularly.

**Spring/Summer 2009.** At its Fort Washington facility, McNeil makes a wide variety of OTC products, including a large number of OTC liquid products for children.

In May and June 2009, FDA identified several cGMP violations, including McNeil’s failure to meet its own standard for quality in one of the ingredients in OTC liquids.

McNeil’s standard for this ingredient, known as microcrystalline cellulose, required that there be no gram negative bacteria. McNeil purchased the cellulose in partial lots that had not tested positive for this objectionable bacteria. The vendor tested other partial lots from the same large master lot and found a certain gram negative bacteria called *B. cepacia*. According to cGMP standards, McNeil should not have used any partial lots from this master lot.

In reviewing the situation, FDA scientists concluded that the risk to the public was remote. All of the drums used tested negative for the bacteria *B. cepacia*, all of the final product tested negative, and FDA agreed with the company’s assessment that this bacteria would be very unlikely to grow in the final product.



Yet, because the company had not kept to its standard, it represented a cGMP violation, and the company initiated a recall of almost eight million bottles of finished product in August 2009.

**Fall 2009.** At its Las Piedras, Puerto Rico, facility, McNeil makes a large number of OTC pills for the U.S. market.

*In the fall of last year, FDA became aware that McNeil had received reports of products from this facility having a musty odor. Yet, McNeil had not fully investigated these reports for about a year and did not notify FDA despite the requirement that such reports be referred to the Agency within three days.*

FDA inspectors urged McNeil to conduct a complete investigation, which eventually identified the source of the odor to be a chemical, called 2,4,6-Tribromoanisole or TBA, which was in the air because of a pesticide used on the wood of the pallets used to store empty medication bottles. McNeil initiated a series of recalls as the scope of the problem became clear.

The risk posed to the public by this problem included potential temporary, non-serious gastrointestinal reactions – including nausea, stomach pain, vomiting, or diarrhea. Very little is known about the chemical TBA, but in the small quantities transferred to the products, it is not thought to pose a serious risk for long-term health problems.

*On January 15, 2010, FDA issued a warning letter to McNeil expressing serious concerns about the company's control over the quality of its drugs and the company's failure to aggressively investigate and correct quality problems. This letter identified significant violations of the cGMP regulations. FDA noted that neither upper management at Johnson & Johnson nor at McNeil assured timely investigation and resolution of the issues.*

**January and February 2010.** In early 2010, FDA conducted focused inspections of McNeil at both the Las Piedras and Fort Washington facilities to follow up on a reported problem. The report identified a 6-year-old child who died. Prior to his death, the child had been given several products manufactured by McNeil at these facilities. FDA tested the products the child had taken for potential contamination, and all results were negative. Based on the results of the testing and the results of the inspection, FDA did not find evidence to link the products to the child's death.

**February 2010.** On February 19, 2010, senior compliance staff from FDA's Center for Drug Evaluation and Research and from FDA's field organization met with senior officials from McNeil and its parent company, Johnson & Johnson. Attendees included the President of McNeil, the Company Group Chairman for OTC at Johnson & Johnson, as well as a number of Quality Assurance executives from both companies.

*This was an extraordinary meeting. FDA requested that senior officials from Johnson & Johnson attend the meeting so they would be on notice regarding FDA's rising concerns about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency and safety of its products. FDA also raised concerns about Johnson & Johnson's oversight of McNeil due to recent multiple recalls of McNeil products and recent warning letters FDA had issued to both McNeil and its parent company, Johnson & Johnson. Based on the Fort Washington and Las Piedras inspections in 2009 as well as the firm's recent compliance history, FDA expressed its significant concern that there was a pattern of conduct including failure to report material information to FDA in a timely manner, miscalculating and/or misstating risks and benefits of their products, and reactive vs. proactive approaches to product quality problems. FDA told the company's leadership that significant, immediate steps were needed to address issues of compliance and quality, especially in investigating product quality issues so that the company could take preventive action to avoid problems.*

The Agency learned that McNeil was taking several major steps to address these issues, including implementing management reporting structure changes, hiring new managers, and engaging a third party manufacturing consultant. FDA indicated that it would continue to monitor closely and consider further action, and that it was concerned about whether the company's corporate culture was appropriately focused on product quality issues.

**April 2010.** In April, FDA inspectors returned to McNeil's Fort Washington facility. This inspection was scheduled sooner than usual due to McNeil's recent history of compliance problems, including numerous recalls and cGMP deficiencies discovered in the June 2009 Fort Washington inspection, which had a significant impact on the scheduling of the April 2010 inspection.

Days before the inspectors arrived, McNeil shut down manufacturing because of manufacturing issues, including particulates found in a number of liquid medications. These particulates included acetaminophen, cellulose, nickel, and chromium. FDA inspectors identified a range of cGMP violations. These included the company failing to meet its own specifications for bacteria and particulates and, for one Tylenol product, the possibility of higher than expected concentrations of Tylenol per dropper.

In reviewing the situation, FDA scientists concluded that the risk posed to the public by these problems was remote. FDA did not find evidence that McNeil used raw materials that its tests found to be positive for bacterial contamination and all lots of finished product were tested by McNeil and found negative for bacterial contamination. The particulates would be expected to pass through the gastrointestinal tract. While there was a potential for higher concentrations of Tylenol per dropper, none of the final products released for sale tested with high

levels. In addition, the increase in potency would not be expected to cause adverse effects.

***Although the public health risk from these quality problems is low, these problems should never have occurred, and the cGMP failures at the facility that caused them were unacceptable.*** Following cGMP requirements assures that products are consistent in their safety and effectiveness and failure to follow those procedures undermines consumer confidence. On April 30, 2010, McNeil announced a voluntary recall of over 136 million bottles of liquid infants' and children's products.

### **Next Steps in FDA Oversight of McNeil**

Based on the pattern of concerns found at McNeil's facilities, FDA is working with the company to address its systemic quality issues. The Agency is closely monitoring the implementation of a corrective action plan developed by McNeil that includes significant enhancements to its quality system, organizational changes, and senior management oversight.

FDA will continue to investigate issues related to the Fort Washington facility including oversight related to renewal of manufacturing operations at that facility, to evaluate the facility's suppliers, and evaluate the compliance of all other McNeil facilities. FDA will also take steps to help ensure that when the facility begins manufacturing again it will be able to produce safe products. ***FDA is also considering additional enforcement actions against the company for its pattern of non-compliance which may include seizure, injunction or criminal penalties.***

\* \* \*

### **Lessons Learned**

Every investigation presents an opportunity for FDA to improve our effectiveness in protecting the public health. One lesson to be drawn from the McNeil story is that it is important for the Agency to even more fully consider the corporate structure when investigating and enforcing the law. FDA will be developing new procedures to use what we learn at one facility in guiding our inspections of other facilities run by the same company.

FDA is also using these events as part of an ongoing review of our recall process. FDA has already made significant changes to its approach to recalls when there are urgent, life-threatening product quality concerns. For example, in recent months, FDA has moved aggressively to support several urgent food recalls. FDA is now looking at our process for clear expectations and standards with respect to other types of recalls, such as those undertaken by McNeil.

We will continue to work with Congress to secure additional authorities that could assist us in assuring product quality and acting more quickly when product quality issues occur.

FDA will also be considering enforcement actions in this case as part of the Agency's ongoing changes in enforcement.

FDA Commissioner Dr. Margaret Hamburg has called for FDA's enforcement to be "vigilant, strategic, quick, and visible." A range of activities are underway at the Agency to bring this vision to reality, including strengthening our criminal enforcement of FDA's laws.

As we continue these efforts, as well as our other regulatory work, we will focus on entire companies and their systems in addition to focusing on specific violations, individuals, and sites, much as we are doing in the McNeil situation.

[Emphasis added.]

119. As evidenced above, J&J fostered a culture at its McNeil subsidiary marked by organizational shortcomings and systemic ethical and legal violations. As a result of this pervasive conduct, the Company has suffered significant damages, including long-term negative implications to its reputation, hundreds of millions of dollars in costs and potential penalties, and significant financial liability.

120. J&J is also causing further harm to its reputation by its failure to cooperate with the Congressional inquiry into its operations. On June 10, 2010, the New York Times published an article entitled, "*Drug Maker Seen as Uncooperative on Inquiry*", in which Representative Edolphus Towns stated "we [Congress] are not getting the kind of information and cooperation from Johnson that I would like."

121. In a closing statement issued by the Committee on Oversight and Government Reform, Towns also lamented J&J's lack of candor in its communications with Congress. "I was hoping that J&J would be completely forthcoming today, but I think there are still unanswered

questions” the statement reads after opening with the troublesome conclusion “Frankly, what we have heard today is not reassuring.”

122. In particular, Towns was troubled by apparent discrepancies in J&J’s accounts of its activities. For example, the Company told members of Towns’ staff that the recall involved 6 million bottles of children’s medicine while it informed the FDA that the recall involved more than *136 million bottles*. Similarly, during an interview in late May 2010, Luther told House investigators that the Fort Washington plant did not make products for other companies; however, four days later Blacksmith Brands, which markets PediaCare children’s medicines announced its own voluntary recall “as a precautionary step” because certain of its cough and cold products were manufactured at McNeil’s Fort Washington plant. Representative Eleanor Holmes Norton, who sits on the House oversight committee said the Company’s conduct seemed to her to demonstrate a continuing lack of transparency. [Emphasis added.]

#### **DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

123. Plaintiffs are current owners of J&J common stock and were owners of J&J common stock during the period relevant to the Individual Defendants’ wrongful course of conduct alleged herein.

124. Plaintiffs bring this action derivatively to redress injuries suffered, and to be suffered, by Plaintiffs as a direct result of the breaches of fiduciary duty, abuse of control, waste of corporate assets, and unjust enrichment by the Individual Defendants.

125. Plaintiffs have not made any demand upon J&J to bring an action on behalf of J&J asserting claims herein to recover damages for the injuries suffered by J&J, since such demand would have been a futile, wasteful and useless act, and is therefore excused, for the reasons stated herein.

126. The J&J Board currently consists of the following ten individuals: Defendants Coleman, Cullen, Johns, Lindquist, Mullin, Perez, Prince, Satcher, Weldon and Anne M. Mulcahy.

127. Together with all of the Individual Defendants, the present Board embraced or recklessly disregarded the Company-wide business strategy based upon repeated and systematic violations of Federal law, safety regulation and Company policy. This strategy was implemented over an extended period of time through multiple divisions of J&J, was carried out at all levels of the Company, and was well-known to the Board and throughout the Company. By permitting these violations of law to continue for over a prolonged period after being put on notice numerous times, the Board at the least failed to exercise adequate oversight over J&J, and thus face a substantial likelihood of liability for much of the conduct complained of herein. By their wrongful acts, the Individual Defendants were unjustly enriched at the expense of and to the detriment of J&J. The Individual Defendants received compensation and/or director remuneration at the same time in which they were breaching their fiduciary duties owed to the Company. Any suit by the current directors of J&J to remedy the wrongs complained of herein would expose the defendants themselves and their friends and business allies to significant personal liability for their breaches of fiduciary duties and other misconduct.

128. Further, the unlawful acts and practices alleged herein cannot be defended by the Individual Defendants and are not subject to the protection of any independent business judgment as they were unlawful or improper and in turn, *ultra vires*. This action does not arise from a single incident, but multiple schemes spanning years that were common knowledge throughout the Company. Serious violations of applicable law and regulations occurred systematically throughout the Company as a direct result of the Board's decision to embrace a policy of calculated legal violations as the Company's deliberate business strategy. There is no legitimate

“business judgment” involved in devising or carrying out such an unlawful policy. The J&J Board approved of or willfully disregarded the improper business strategy described herein. The approval of action by the Company that violates applicable law can never be protected by the business judgment rule. Nor can such malfeasance ever constitute the “good faith” required of corporate fiduciaries. Accordingly, demand on the Board is excused.

129. Demand is also excused because the wrongs alleged herein constitute violations of the Company’s internal policies and charters and cannot be considered a valid exercise of business judgment.

130. The Individual Defendants’ wrongful conduct was continuous and occurred both before and throughout the Relevant Period. It resulted in ongoing and continuous harm to the Company. The Individual Defendants participated in and/or failed to adequately address, correct and/or disclose such conduct.

131. In addition, demand is also excused because the Individual Defendants have ratified the egregious actions outlined herein, they cannot be expected to prosecute claims against themselves and/or persons or entities with whom they have extensive inter-related business and professional and personal entanglements, including the other Individual Defendants, if Plaintiffs demanded that they do so. The Individual Defendants, because of these relationships, have developed debilitating conflicts of interest that prevent them from taking the necessary and proper action on behalf of J&J.

132. Demand is also excused because the Individual Defendants participated in, approved or permitted the wrongs alleged herein, concealed or disguised those wrongs, or recklessly or negligently disregarded them, and are therefore not a disinterested party and lack sufficient independence to exercise business judgment as alleged herein. As evidenced by the

Congressional statement described herein, J&J has not been forthcoming about the McNeil recalls and similar incidents, and there is no reason to believe the Board would take due action upon shareholder demand.

133. The Company has been directly and substantially injured by reason of the Individual Defendants' intentional breach and/or reckless disregard of their fiduciary duties to the J&J. Plaintiffs, as shareholders of the Company, seek damages and other relief on behalf of J&J, in an amount to be proven at trial.

**COUNT I**  
**(Breach of Fiduciary Duty)**

134. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

135. The Individual Defendants owed a fiduciary duty to J&J to supervise the issuance of its press releases and public filings and ensure that they were truthful, accurate and conformed to federal and state securities law. The Individual Defendants breached their fiduciary duties by failing to properly supervise and monitor the adequacy of J&J's internal controls and by allowing misleading statements and filings to be issued.

136. The Individual Defendants have engaged, knowingly or recklessly, in a sustained and systematic failure to exercise their oversight responsibilities to ensure that J&J complied with federal and state laws, rules and regulations.

137. As members of the J&J Board, the Individual Defendants were directly responsible for authorizing or permitting the authorization of, or failing to monitor, the practices which resulted in violations of the federal and state laws as alleged herein. Each of them had knowledge of and actively participated in and/or approved of or acquiesced in the wrongdoings



alleged herein or abdicated his/her responsibilities with respect to these wrongdoings. The alleged acts of wrongdoing have subjected J&J to unreasonable risks of loss and expenses.

138. Each of the Individual Defendants' acts in causing or permitting the Company to disseminate to the investing public material misrepresentations and omissions and abdicating their oversight responsibilities to the Company has subjected the Company to liability for violations of federal and state law, and therefore was not the product of a valid exercise of business judgment and was a complete abdication of their duties as officers and/or directors of the Company. As a result of the Individual Defendants' breaches, J&J has lost market capitalization and has had its reputation in the business community and financial markets irreparably tarnished.

139. By reason of the foregoing, J&J was damaged.

140. Plaintiffs, on behalf of J&J, have no adequate remedy at law.

## **COUNT II** **(Gross Mismanagement)**

141. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

142. The Individual Defendants had a duty to J&J and its shareholders to prudently supervise, manage and control the operations, business and internal financial accounting and disclosure controls of the Company.

143. The Individual Defendants, by their actions and be engaging in the wrongdoing described herein, abandoned and abdicated their responsibilities and duties with regard to prudently managing the business of J&J in a manner consistent with the duties imposed upon them by law. By committing the misconduct alleged herein, the Individual Defendants breached

their duties of due care, diligence, and candor in the management and administration of J&J's affairs and in the use and preservation of the Company's assets.

144. During the course of the discharge of their duties, the Individual Defendants knew or recklessly disregarded the unreasonable risks and losses associated with their misconduct, yet the Individual Defendants caused J&J to engage in the scheme complained of herein, which they knew had an unreasonable risk of damage to J&J, thus breaching their duties to the Company. As a result, the Individual Defendants grossly mismanaged J&J.

145. By reason of the foregoing, J&J was damaged.

146. Plaintiffs, on behalf of J&J, have no adequate remedy at law.

**COUNT III**  
**(Contribution and Indemnification)**

147. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

148. J&J is alleged to be liable to various persons, entities and/or classes by virtue of the same facts or circumstances as are alleged herein that give rise to Defendants' liability to J&J.

149. J&J's alleged liability on account of the wrongful acts, practices and related misconduct described above arises, in whole or in part, from the knowing, reckless, disloyal and/or bad faith acts or omissions of the Individual Defendants as alleged above, and J&J is entitled to contribution and indemnification from each Individual Defendant in connection with all such claims that have been, are or may in the future be asserted against, J&J by virtue of the Individual Defendants' misconduct.

150. By reason of the foregoing, J&J was damaged.

151. Plaintiffs, on behalf of J&J, have no adequate remedy at law.

**COUNT IV**  
**(Unjust Enrichment)**

152. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

153. Through the wrongful course of conduct and actions complained of herein, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, J&J. The wrongful conduct was continuous and resulted in ongoing harm to the Company. The Individual Defendants were unjustly enriched pursuant to receiving compensation and director remuneration while breaching their fiduciary duties to the Company.

154. Plaintiffs, as shareholders of J&J, seek restitution from the Individual Defendants, and seek an order of this Court disgorging all profits, benefits, and other compensation obtained by the Individual Defendants, from their wrongful course of conduct and fiduciary breaches.

155. By reason of the foregoing, J&J was damaged.

156. Plaintiffs, on behalf of J&J, have no adequate remedy at law.

WHEREFORE, Plaintiffs demand judgment as follows:

- (a) Directing the Individual Defendants to account to J&J for all damages sustained or to be sustained by the Company by reason of the wrongs alleged herein;
- (b) Requiring the Individual Defendants to return to J&J all salaries and the value of other remuneration of whatever kind paid to them by the Company during the time they were in breach of the fiduciary duties they owed to J&J;
- (c) Requiring the Company to take remedial measures related to the wrongs alleged herein, including corporate reform, periodic third party review of operations or other endeavors the Court sees fit or the parties agree upon;

- (d) Directing the Individual Defendants to pay interest at the highest rate allowable by law on the amount of damages sustained by the Company as a result of the Individual Defendants' culpable conduct;
- (e) Awarding Plaintiffs the costs and disbursements of this action, including reasonable attorneys' and experts' fees and expenses; and
- (f) Granting such other and further relief as the Court may deem just and proper.

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Attorneys for Plaintiffs

By: /s/ James E. Cecchi  
JAMES E. CECCHI

Dated: June 24, 2010

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**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury as to all issues so triable.

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**VERIFICATION**

I, Walter Schirmer, pursuant to U.S. Code Title 28, Section 1746, hereby declare as follows:

I am authorized to make this verification by the plaintiff herein and that the facts and allegations therein contained in the foregoing Verified Shareholder Derivative Complaint are true and correct to the best of my information and belief based upon discussions with and reliance upon my counsel. Plaintiff is a shareholder of Johnson & Johnson, was a shareholder at the time of the wrongdoing complained of and remains a shareholder. I have retained competent counsel and I am ready, willing and able to pursue this action vigorously on behalf of Johnson & Johnson.

I declare under penalty of perjury that the foregoing is true and correct.

Signed and Accepted:

Date: 6-22-10

  
Walter Schirmer

**NOTARIZED VERIFICATION**

I, Steven Myers, verify on behalf of the NECA-IBEW Pension Trust Fund and NECA-IBEW Welfare Trust Fund (hereinafter collectively as "NECA IBEW," that I have reviewed the foregoing Verified Shareholder Derivative Complaint on behalf of nominal defendant Johnson & Johnson, and that the allegations as to the NECA-IBEW and its own actions are true and correct and that the other allegations upon information and belief are true and correct.

Dated: June 22, 2010

Steven J. Myers (Signature of Steven Myers)

SWORN TO AND SUBSCRIBED before me this 22<sup>nd</sup> day of June, 2010

Robin K. Hamilton  
Notary Public

My Commission Expires: 10/10/11

